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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,218	08/18/2000	Olga Yurieva	600-1-179N CON	6461

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,218

Applicant(s)

YURIEVA ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/7/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,22,28,29 and 81-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,22,28,29,81,83-86,88 and 89 is/are rejected.
- 7) ☒ Claim(s) 8, 82, 87 and 90 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/18/2000 & 9/7/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment of claim 7, cancellation of claims 9, 10, 44, 45, 52, 61, 71-80, and the addition of new claims 81-90 in the paper of 9/7/2004, is acknowledged. Claims 7, 8, 22, 28, 29 and 81-90 are still at issue and are present for examination.

Claim Objections

Claims 8, 82, 87 and 90 are objected to because of the following informalities:

Claims 8, 82, 87 and 90 are dependent on rejected claim 7.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 22, 28, 29, 81, 83-86, 88 and 89 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 38-41, 44, 45, 48, 52, 61 and 68-72. In response to this rejection

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applicants have cancelled claims 38-41, 44, 45, 48, 52, 61 and 68-72 and added new claims 81-90 and traverse the rejection as it applies to the newly amended claims. Additionally applicants have amended claim 7. It is noted that applicants amendment of claim 7 has resulted in the inclusion of claims 7, 22, 28 and 29 and 81-90 in the rejection and applicants have not traversed the rejection with respect to these newly rejected claims.

Claims 7, 22, 28 and 29, are directed to all possible isolated polynucleotides encoding a τ or γ subunit of a DNA polymerase III-type enzyme of a thermophilic bacterium, wherein said polynucleotide is at least 90 percent identical to the nucleotide sequence of SEQ ID NO: 3 and vectors and host cells comprising said polynucleotide

There is no disclosure of any particular structure to function/activity relationship in the disclosed species encompassed by the rejected claims. The specification also fails to describe additional representative species of these polynucleotides and the encoded polypeptides by any identifying structural characteristics or properties other than the activities and molecular weight, recited in the claims, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 7, 22, 28, 29, 81, 83-86, 88 and 89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding a τ or γ subunit of a DNA polymerase III-type enzyme, wherein said τ or γ subunit has an amino acid residue sequence represented by the formula shown in SEQ ID NO: 2 or SEQ ID NO: 4, does not reasonably provide enablement for any polynucleotide encoding a τ or γ subunit of a DNA polymerase III-type enzyme of a thermophilic bacterium, wherein said polynucleotide is a mere 90% identical to the nucleotide sequence of SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 7-10, 22, 28, 29, 44, 45 and 52, 61, 68-72, and 74-80. In response to this rejection applicants have amended claim 7, cancelled claims 38-41, 44, 45, 48, 52, 61 and 68-72 and added new claims 81-90 and traverse the rejection as it applies to the newly amended/added claims. Claims 81, 83-86, 88 and 89 are included in the rejection for the same reasons previously stated for claims 7-10, 22, 28, 29, 44, 45 and 52, 61, 68-72, and 74-80.

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Applicants continue to traverse the rejection on the basis that all that is needed is objective enablement of what is claimed and the present application provides the nucleotide sequence of a *Thermus thermophilus* dnaX (e.g., SEQ ID NOs: 1 and 3) and describes how one of ordinary skill can isolate other homologs of the disclosed sequence, and express the tau and gamma subunits and test the subunits for activity.

Applicants continue to argue that the rejection under 35 U.S.C. §112, first paragraph is not proper because the specification teaches the complete nucleotide sequences of a *Thermus thermophilus* dnaX, protocols for using the DNA of SEQ ID NO:1 as a probe, and protocols for testing for the encoded proteins activity as well as methods of identifying and producing variants of *T. thermophilus* Pol III γ and τ subunits are known by those skilled in the art. Applicants support their assertions regarding methods of identifying and producing variants by presenting the publication by McHenry et al.

Applicants complete argument has been considered, however, not found persuasive for the reasons previously stated and repeated below.

While methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a DNA polymerase type-III subunit) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the larger number of variants have the desired properties. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually

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infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting τ or γ subunit activity; (B) the general tolerance of τ or γ subunits to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a DNA polymerase III enzyme τ or γ subunit with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the delta subunit activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those DNA molecules of the claimed genus which encode a polypeptide with DNA polymerase III enzyme τ or γ subunit activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed

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DNA molecules from a thermophilic bacterium, encoding a DNA polymerase III-type enzyme τ or γ subunit. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polynucleotides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

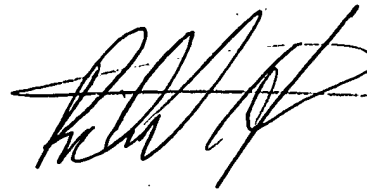
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
7/20/2005